REMARKS

The current application relates to a container comprising an immunologically isolated genetically altered bone marrow stromal cell. Claims 69-70, 97-108, 112, and 113 are currently pending in the present application. Claims 72-76, 78-96, and 109-111 were canceled in the two previous Responses to the previous Office Actions, filed February 7, 2002 and November 8, 2002, respectively. Claims 71 and 77 were canceled herein, without prejudice to the inclusion of the subject matter contained therein in any later-filed divisional or continuation application.

Applicants would like to thank the Examiner for the opportunity to conduct a telephonic interview on May 27, 2003. As a result of the interview, the Examiner has graciously provided Applicants with suggested amendments to claim 69 which would render claim 69 allowable and overcome the two outstanding rejections under §112, first paragraph, enablement and §103. Applicants appreciate the Examiner's efforts in preparing an allowable claim; however, Applicants respectfully disagree that the suggested amendment to claim 69 is the most accurate reflection of Applicants' invention. Applicants have amended claims 69, 102-104, and 112 as described herein to accurately reflect Applicants' invention, and submit that the claims, as amended, are independently allowable over the Examiner's proposed amendment for the reasons more fully discussed below.

Support for the Amendments to the Claims

Applicants have amended claim 69 to include a limitation similar to that in the proposed allowable claim drawn up by the Examiner. The limitation includes "a second expressible gene construct encoding a cytotoxic protein, which cytotoxic protein induces selective cell death in the presence of a drug specific for said cytotoxic protein." Support for this limitation can be found on page 20, lines 6-25 of the specification. Specifically, lines 8-10 state that bone marrow stromal cells may be "provided with genes that encode a receptor that can be specifically targeted with a cytotoxic agent." Lines 11-15 on page 20 go on to state that bone marrow stromal cells expressing a protein, such as, for example, herpes tk, encoded by a gene that can be used to induce selective cell death, are susceptible to targeted killing in the presence of specific agents, such as, for example, gangcyclovir (a drug specific for herpes tk).

Applicants contend that the term "receptor" used in line 9 on page 20 of the

application includes any ligand, including a cytotoxic protein, that can be specifically targeted with a cytotoxic agent, i.e., that can "receive" a cytotoxic agent. In addition, the term "cytotoxic agent" includes within its definition any agent capable of targeting the ligand, including a cytotoxic drug. This is exemplified by the example presented in the application of using herpes tk as the cytotoxic protein and gangcyclovir as the cytotoxic drug. Applicants further submit that one of skill in the art would understand, based upon the disclosure presented in the application, that any targeted cell death system known in the art would work with the present invention.

Claims 102-104 and 112 were amended to reflect the amendments to claim 69.

Applicants submit that the amended claims meet the requirements for patentability set forth in 35 U.S.C. §112, as described herein.

Rejection of claims 69 and 77 under 35 U.S.C. §112, first paragraph

Claims 69 and 77 has been rejected under 35 U.S.C. 112, for lacking enablement. The Examiner has indicated that cancellation of claim 77 would obviate the rejection, and Applicants have canceled claim 77 in light of the Examiner's suggestion. Therefore, this rejection is rendered moot. Applicants respectfully request withdrawal of this rejection.

Rejection of claims 69-71, 99-108, 112, and 113 under 35 U.S.C. §103

Claims 69-71, 99-108, 112, and 113 have been rejected by the Examiner as being obvious in view of Naughton (Som. Cell and Mol. Gen.; 18(5):451-462; "Naughton I") taken in combination with any of Naughton et al. (U.S. Pat. No. 5,858,721; "Naughton II"); Caplan, et al. (U.S. Pat. No. 5,197,985); Schinstine et al. (U.S. Pat. No. 5,843,431); Mardon (previously cited); and Applicant's statement of the prior art on page 6 through page 7, and page 27 of the specification. Applicants respectfully traverse the Examiner's rejection.

Applicants have amended claim 69 to recite that the bone marrow stromal cell in the container comprises a second expressible gene construct encoding a cytotoxic protein. The bone marrow stromal cell comprising the cytotoxic protein gene construct can be selectively destroyed by administering a drug specific for the cytotoxic protein.

This limitation is neither taught nor suggested in any of the references cited by the Examiner. As the Examiner already conceded in drafting his proposed allowable claim, a container comprising a bone marrow stromal cell encoding a receptor of a cytotoxic drug in addition to the limitations already present in the claim, is allowable. Therefore, Applicants

submit that claim 69, as amended herein, is also allowable, as more fully discussed in the "Support for the Amendments to the Claims" section. Applicants respectfully request reconsideration and withdrawal of the rejection.

Summary

Applicants respectfully submit that each rejection of the Examiner to the claims of the present application has either been overcome or is now inapplicable, and that each of claims 69-71, 97-108, 112, and 113 is in condition for allowance. Reconsideration and allowance of each of these claims are respectfully requested at the earliest possible date.

Respectfully submitted,

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